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STATE OF MAINE
DEPARTMENT OF ENVIRONMENTAL PROTECTION

JOHN ELIAS BALDACCI
GOVERNOR

DAVID P. LITTELL
COMMISSIONER

Memorandum

TO: Board of Environmental Protection

FROM: Andrea Lani, Bureau of Remediation & Waste Management

DATE: September 2, 2010

RE: Posting to Public Hearing: Chapter 883, Designation of the Chemical Class Nonylphenol and Nonylphenol Ethoxylates as a Priority Chemical.

Statutory and Regulatory Reference:

A. Statutory authority.

38 MRSA §§1691 through 1699-B.

B. Specific legal mandates requiring adoption.

38 MRSA §1695 requires the commissioner to designate at least two priority chemicals by January 1, 2011. The department's regulation 06-096 Chapter 880, *Regulation of Chemical Use in Children's Products* section 2(D) requires that designation of a priority chemical be done through the adoption of a rule. This rulemaking constitutes the second of the two required designations.

Location/Applicability:

The proposed regulation will apply statewide.

Description:

The proposed regulation will:

- Designate the chemical class nonylphenol and nonylphenol ethoxylates as a priority chemical; and
- Require manufacturers of certain consumer products that contain nonylphenol or nonylphenol ethoxylates to submit information to the department on the extent to which these chemicals are used in and the likelihood that children will be exposed to them as a result of its presence in those products.

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Environmental Issues:

Nonylphenol and nonylphenol ethoxylates have been detected in the natural environment, including ambient air, sewage treatment plant effluent, sediment, soil and surface waters, as well as in wildlife, household dust and human tissues. Nonylphenol and nonylphenol ethoxylates are toxic to aquatic organisms, and the breakdown products of nonylphenol ethoxylates (NP and shorter-chained ethoxylates) are more toxic and more persistent than their parent chemicals.

Nonylphenol has been shown to mimic natural hormones by interacting with the estrogen receptor. Estrogenic effects have been demonstrated in a number of aquatic organisms, rats and in human breast tumor cells.

Departmental Recommendation:

The Department recommends that the Board schedule a public hearing on the proposed rule for October 7, 2010 and proposes a public comment period deadline of October 18, 2010.

Estimated Time of Presentation:

20 minutes.

DRAFT

Chapter 883: DESIGNATION OF THE CHEMICAL CLASS NONYLPHENOL AND NONYLPHENOL ETHOXYLATES A AS A PRIORITY CHEMICAL

SUMMARY: This rule designates the chemical class nonylphenol and nonylphenol ethoxylates as a priority chemical and requires reporting for certain product categories that contain a chemical compound in the class.

1. **Applicability.** This chapter applies to manufacturers of children's products containing intentionally-added nonylphenol or nonylphenol ethoxylates that are manufactured, sold, offered for sale or distributed for sale in Maine.

2. **Definitions.** For terms not defined in this rule, the definitions found in 06-096 CMR Chapter 880, *Regulation of Chemical Use in Children's Products*, section 1, apply. The following terms, as used in this rule, have the following meanings:

   A. **Cosmetics and personal care products.** "Cosmetics and personal care products" means articles intended to be rubbed, poured, sprinkled, or sprayed on, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and articles intended for use as a component of any such articles.

   B. **Household and commercial cleaning products.** "Household and commercial cleaning products" means soaps, detergents and other chemically formulated consumer products designed for fabric care, dish and other ware washing and/or surface cleaning in residential, institutional or commercial establishments.

   C. **Exposure or exposed.** "Exposure or exposed" in reference to a priority chemical means that a person is subjected in the course of daily life to a priority chemical from a product that enters the body in any quantity from any route of entry, including inhalation, ingestion, skin contact or absorption.

   D. **Home maintenance products.** "Home maintenance products" means products used for the repair or maintenance of the inside or outside of a home, including, but not limited to, adhesives, caulking, grouts, fillers, sealants, paints and other surface finishes.

   E. **Nonylphenol (NP) and nonylphenol ethoxylates (NPE).** "Nonylphenol (NP) and nonylphenol ethoxylates (NPE)" means nonionic surfactants in the alkylphenol and alkylphenol ethoxylate group of chemical compounds. Nonylphenol has a chemical formula of C15-H24-O and may be linear (Phenol, nonyl-), with a Chemical Abstract Service Registry Number (CAS RN) of 25154-52-3, or branched (phenol, 4-nonyl-, branched), with a CAS RN of 84852-15-3. The formula for chemicals in the nonylphenol ethoxylate group is (C2-H4-O)mult-C15-H24-O, and commercially-relevant CAS RNs include, but are not limited to: 9016-45-9, 26027-38-3, 37205-87-1, 68412-54-4, and 127087-87-0.

3. **Designation of the chemical class nonylphenol and nonylphenol ethoxylates as a priority chemical**

   A. **Presence on chemicals of high concern list.** The chemical class nonylphenol and nonylphenol ethoxylates is on the list of chemicals of high concern published by the department under 38 MRSA §1693.

   NOTE: To view the full list, go to: www.maine.gov/dep/oc/safechem/highconcern/

   B. **Criteria for designation.** The following criteria for designation of the chemical class nonylphenol and nonylphenol ethoxylates as a priority chemical, as set forth under 38 MRSA §1694, have been met as documented in the basis statement accompanying this chapter:

(a) Chemicals from the class or their metabolites have been found through biomonitoring to be present in human blood, including umbilical cord blood, breast milk, urine or other bodily tissues or fluids;

(b) Chemicals from the class or their breakdown products have been found through sampling and analysis to be present in household dust, indoor air, drinking water or elsewhere in the home environment;

(c) Chemicals from the class or their breakdown products have been found through monitoring to be present in fish, wildlife and the natural environment;

(d) Chemicals from the class are present in a consumer product used and present in the home; and

(e) Nonylphenol and nonylphenol ethoxylates have been identified as a high production volume chemical by the federal Environmental Protection Agency.

4. Information submission required.

A. Product categories. Manufacturers of the following products that contain intentionally-added nonylphenol or nonylphenol ethoxylates must submit information to the department pursuant to section 4(B) of this chapter:

(1) Household and commercial cleaning products,

(2) Cosmetics and personal care products, and

(3) Home maintenance products sold, marketed to or intended for use by consumers.

B. Information required. No later than 180 days after the effective date of this rule, the manufacturer of a consumer product listed in section 4(A) of this chapter that contains intentionally-added nonylphenol or nonylphenol ethoxylates, shall report to the department the following information:

(1) The name and address of the manufacturer and the name, address, and phone number of a contact person for the manufacturer;

(2) A description of the manufacturer's product or products containing nonylphenol, nonylphenol ethoxylates or related substances;

(3) The amount of nonylphenol, nonylphenol ethoxylates or related substances in each unit of the product;

(4) The function of nonylphenol, nonylphenol ethoxylates or related substances in the product;

(5) The number of product units sold or distributed in Maine or nationally, expressed as a range;

(6) Any assessment that has already been performed by the manufacturer of the availability, cost, feasibility and/or performance, including potential for harm to human health and the environment, of alternatives to nonylphenol, nonylphenol ethoxylates or related substances

and the reason nonylphenol, nonylphenol ethoxylates or related substances are used in the manufacture of the children's product in lieu of identified alternatives; and

(7) Other information the manufacturer deems relevant to the reporting of the chemical.

NOTE: Upon review of information submitted pursuant to this chapter, the commissioner may request that a manufacturer clarify the submittal, supplement incomplete information or provide additional information not specified in this chapter if the commissioner determines that the information is needed for the department to complete its evaluation of the priority chemical. See department rules, 06-096 CMR 880(3)(D); see also 38 MRSA §1695(2).

5. **Department Address**. Information submissions may be made by regular or electronic mail. The department may provide electronic or paper reporting forms. Use the following address to send all non-electronic correspondence to the department:

Maine Department of Environmental Protection
Bureau of Remediation and Waste Management, Safer Chemicals Program
17 State House Station
Augusta, ME 04333

NOTE: Electronic reporting forms and/or email addresses for reporting will be provided at: www.maine.gov/dep/oc/safechem/index.htm

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BASIS STATEMENT FOR
CHAPTER 883, DESIGNATION OF THE CHEMICAL CLASS NONYLPHENOL AND NONYLPHENOL ETHOXYLATES AS A PRIORITY CHEMICAL

AND

SAFER CHEMICALS PROGRAM SUPPORT DOCUMENT FOR THE DESIGNATION AS A PRIORITY CHEMICAL OF

Nonylphenol and Nonylphenol Ethoxylates

Prepared by Andrea Lani
Bureau of Remediation and Waste Management
Maine Department of Environmental Protection

September 2, 2010

PREFACE

In April 2008, the Legislature adopted Public Law Chapter 643, *An Act to Protect Children's Health and the Environment from Toxic Chemicals in Toys and Children's Products* [38 MRSA §§1691 through 1699-B]. The goal of the law as set forth in the Legislature's Declaration of Policy under 38 MRSA §1692 is to reduce the exposure of children and other vulnerable populations to chemicals of high concern by substituting safer alternatives when feasible. To accomplish this goal, the law confers upon the department the regulatory power to collect information on chemical use and prohibit the sale of children's products containing priority chemicals when safer alternatives are available.

The Board of Environmental Protection adopted regulations to implement the law in February 2010. Chapter 880, *Regulation of Chemical Use in Children's Products* established rulemaking as the process by which the department will designate priority chemicals. The law and rule require that a substance meet certain criteria in order to be designated a Priority Chemical, and that the department provide findings of fact in support of a proposed designation. This document serves as the support document providing the findings of fact required for designation of the chemical class nonylphenol and nonylphenol ethoxylates as a Priority Chemical, as well as the Basis Statement for the department's proposed Chapter 883, *Designation of the Chemical Class Nonylphenol and Nonylphenol Ethoxylates as a Priority Chemical.*

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INTRODUCTION

Through this rulemaking, the Department of Environmental Protection (department) designates the chemical class of nonylphenol (NP) and nonylphenol ethoxylates (NPE) as a Priority Chemical and requests information on use of this chemical in certain consumer products.

Nonylphenol and nonylphenol ethoxylates are listed on the Chemicals of High Concern list because these chemicals have been identified as endocrine disruptors. Additionally, nonylphenol has been identified as persistent, bioaccumulative and toxic. NP and NPE are the most widely-used members of the larger alkylphenol and alkylphenol ethoxylate family of nonionic surfactants. NP demonstrates estrogenic and endocrine disrupting characteristics and is toxic to aquatic organisms and moderately persistent in the environment. The metabolites and degradation products of NPE are more toxic than the parent compounds. NP has been detected in human tissues and in household dust, as well as in environmental media. The European Union has effectively eliminated use of NP/NPE in most industrial and product sectors and Canada has implemented a pollution prevention plan designed to drastically reduce use of NP/NPE.

The department is proposing to designate nonylphenol and nonylphenol ethoxylates as a priority chemical in accordance with 38 MRSA §1694 and gather information on certain specified uses of the chemical.

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NONYLPHENOL AND NONYLPHENOL ETHOXYLATES

IDENTITY

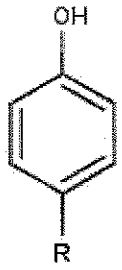
The chemicals described in this section are those that APERC (the Alkylphenols & Ethoxylates Research Council, an association composed of manufacturers, processors, users and raw material suppliers of alkylphenols) considers commercially relevant. However, department designation of nonylphenol and nonylphenol ethoxylates as a priority chemical is not limited to the chemical structures or CAS RNs (Chemical Abstract Service Registry Numbers) listed below.

Nonylphenol: Phenol, 4-nonyl-, branched

CAS Registry Number: 84852-15-3

Chemical Formula: C15-H24-O

Structural Formula:



Select Names and Synonyms for phenol, 4-nonyl, branched:

Branched p-nonylphenol
C9 branched alkyl phenol
EINECS 284-325-5
Nonylphenol
Phenol, 4-nonyl-, branched
p-Nonylphenol, branched

Systematic Name
Phenol, 4-nonyl-, branched

Superlist Name
Nonylphenol, 4-branched
Phenol, 4-nonyl-, branched

Nonylphenol ethoxylates: Polyethylene glycol nonylphenyl ether

Select CAS Registry Numbers:[a]

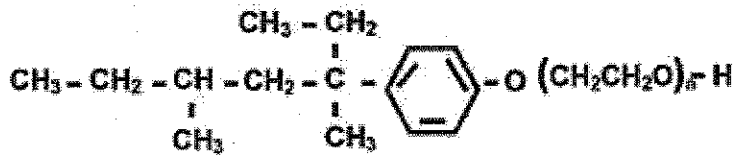
9016-45-9	Poly (oxy-1,2-ethanediyl), *alpha*-(nonylphenyl)-*omega*-hydroxy-
26027-38-3	Poly (oxy-1,2-ethanediyl), *alpha*-(4-nonylphenyl)-*omega*-hydroxy-
37205-87-1	Poly (oxy-1,2-ethanediyl), *alpha*-(isononylphenyl)-*omega*-hydroxy-
68412-54-4	Poly (oxy-1,2-ethanediyl), *alpha*-(nonylphenyl)-*omega*-hydroxy-, branched
127087-87-0	Poly (oxy-1,2-ethanediyl), *alpha*-(4-nonylphenyl)-*omega*-hydroxy-, branched

Chemical Formula: (C2-H4-O)mult-C15-H24-O

Structural Formula:[1]

Nonylphenol Derivative

Nonylphenol Ethoxylate



n = 1 - 100

[a] The CAS RNs listed for NPE are those that are known to APERC to be commercially relevant.

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Select Names and Synonyms:

Names

Nonoxynol-3
Nonoxynol-30
Nonoxynol-4
Nonoxynol-44
PEG-13 Nonyl phenyl ether
PEG-15 Nonyl phenyl ether
PEG-3 Nonyl phenyl ether
PEG-30 Nonyl phenyl ether
PEG-4 Nonyl phenyl ether
PEG-44 Nonyl phenyl ether
Polyethylene glycol (13) nonyl phenyl ether
Polyethylene glycol (15) nonyl phenyl ether
Polyethylene glycol (3) nonyl phenyl ether
Polyethylene glycol (30) nonyl phenyl ether
Polyethylene glycol (44) nonyl phenyl ether
Polyethylene glycol 200 nonyl phenyl ether
Polyethylene glycol nonylphenyl ether
Polyoxyethylene (13) nonyl phenyl ether
Polyoxyethylene (15) nonyl phenyl ether
Polyoxyethylene (3) nonyl phenyl ether
Polyoxyethylene (30) nonyl phenyl ether
Polyoxyethylene (4) nonyl phenyl ether
Polyoxyethylene (44) nonyl phenyl ether

Synonyms

(Nonylphenoxy)polyethylene oxide
A 730
A 730 (surfactant)
Adekatol NP
Adekatol NP 1000
Adekatol NP 1100
Adekatol NP 638
Adekatol NP 650
Adekatol NP 660
Adekatol NP 675
Adekatol NP 683
Adekatol NP 686
Adekatol NP 690
Adekatol NP 700
Adekatol NP 710
Adekatol NP 720
Adekatol NP 760
Adekatol NP 900
Afilan CVH
Agral
Agral 600
Agral 90
Agral LN
Agral Plus
Agral R
Akyporox NP 105
Akyporox NP 95
Alcosist PN
Alfenol
Alfenol 10
Alfenol 18
Alfenol 22
Alfenol 28
Alfenol 710
Alfenol 8
Alfenol N 8
Alkasurf NP
Alkasurf NP 11
Alkasurf NP 15
Alkasurf NP 8
Antarox 897
Antarox CO
Antarox CO 430
Antarox CO 530
Antarox CO 630
Antarox CO 730
Antarox CO 850
Arkopal N-090
Carsonon N-9
Caswell No. 605
Chemax NP series
Conco NI-90
Dowfax 9N20
EPA Pesticide Chemical Code 079005
Emulgen - 913
Ethoxylated nonylphenol
Glycols, polyethylene, monononylphenyl ether
HSDB 6825
Igepal CO-630
Lissapol NX
Neutronyx 600
Nonoxinolum
Nonoxinolum [INN-Latin]
Nonyl phenyl polyethylene glycol
Nonyl phenyl polyethylene glycol ether
Nonylphenol, polyoxyethylene ether

Nonylphenoxypoly(ethyleneoxy)ethanol, branched
Nonylphenoxypolyethoxyethanol
PEG-9 nonyl phenyl ether
Polyethylene glycol 450 nonyl phenyl ether
Polyethylene glycol nonylphenyl ether
Polyoxyethylene (9) nonyl phenyl ether
Polyoxyethylene nonylphenol
Polyoxyethylene(30) nonylphenyl ether
Protachem 630
Rewopol HV-9
Synperonic NX
Tergetol NP
Tergitol NP-10
Tergitol NPX
Tergitol TP-9 (nonionic)
Triton N-100
Trycol NP-1
alpha-(Nonylphenyl)-omega-hydroxypoly(oxy-1,2-ethanediyl)
alpha-(Nonylphenyl)-omega-hydroxypolyoxyethylene
omega-Hydroxy-alpha-(nonylphenyl)poly(oxy-1,2-ethanediyl)

Systematic Name
Agral 90
Glycols, polyethylene mono(nonylphenyl) ether (nonionic)
Glycols, polyethylene, mono(nonylphenyl) ether
Poly(oxy-1,2-ethanediyl), alpha-(nonylphenyl)-omega-hydroxy-
Prevocel #12
Tergitol NP-14
Tergitol NP-27
Tergitol NP-33 (nonionic)
Tergitol NP-35 (nonionic)
Tergitol NP-40 (nonionic)

Superlist Name
Nonyl phenol, ethoxylated
Nonylphenoxypolyethoxyethanol
Poly(oxy-1,2-ethanediyl), alpha-(nonylphenyl)-omega-hydroxy-
Polyoxyethylene nonylphenol

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BACKGROUND

Surfactants are substances that lower the surface tension of water. Structurally, surfactants are made up of a hydrophilic "head" and a hydrophobic "tail." This structure allows the chemicals to absorb dirt and keep it emulsified in the cleaning solution. Surfactants may have a positively-charged head (cationic), a negatively-charged head (anionic) or no charge (nonionic).

The most widely-used of the nonionic surfactants are alkylphenols and alkylphenol ethoxylates, with nonylphenol (NP) making up approximately 85% of the alkylphenol market and nonylphenol ethoxylate (NPE) making up more than 80% of the alkylphenol ethoxylate market in North America.[2]

NP is used as a chemical intermediate in the production of nonylphenol ethoxylates and other compounds [i.e., tris(nonylphenyl) phosphite and nonylphenol-formaldehyde condensation resins]. NP is reacted with ethylene oxide to form variety of NPE isomers (compounds with the same molecular formula but different structural formulae) with different chain lengths. The association representing APE manufacturers states that commercially available NPE have essentially the same structure and isomeric mix, due to manufacturers using basically the same starting materials and synthesis process.[3]

NPE surfactants are used as emulsifiers, wetting agents, dispersants, foam control agents and surface tension agents in commercial and household detergents and cleaning products and are used in industrial applications such as paper and textile manufacture, paints, resins, adhesives and coatings and industrial cleaners.[4] NP may also be used as a plastic additive in modified polystyrene and polyvinyl chloride.[5]

One industry website lists at least 13 different NPE commercial mixtures and categorizes them into a number of uses: adhesives/sealants, wetting agents and stabilizers; agricultural emulsifiers, wetting agents and dispersants; antifog and antistat agent for plastic films; asphalt emulsions; defoamer; dust control agent for coal and mining operations; emulsifier; household applications; industrial and institutional cleaners; leather hide soaking, tanning and dyeing operations; metalworking fluids; oil field chemicals; paints/coatings and emulsion polymerization; pulp/paper deinking, felt cleaning and processing aids; and textile processing. The "household applications" category includes the following product types: all purpose cleaners and degreasers; car wash and car care products; laundry detergents; prewash spot removers; and solid toilet bowl cleaners.[6]

The US Department of Human Services Household Product Database lists numerous household products containing NP or NPE, including home maintenance products (e.g., concrete cleaner, joint sealant, floor coating); "inside the home" products (e.g., laundry detergent, floor stripper, spot and stain pre-treatment, tile cleaner); personal care products (e.g., hair color, mousse and conditioner); as well as automotive products and pesticides. Many of the personal care products are listed as "old product," indicating that NPE may not be used in these products at this time.[7]

In the early 2000s, household cleaning products accounted for 15% of the APE market,[8] however, the industry association representing manufacturers of APE indicated in comments to the department that use of NPE in household cleaning products has decreased.[9]

A background report on the industries that manufacture, import, and/or use NP and NPE completed for Canada in 2000 indicated that the cleaning products sector was responsible for approximately 60% of the total Canadian NP/NPE market, and that end-users of these products were responsible for about 75% of total NP/NPE releases to the environment in Canada.[10]

US EPA Inventory Update Reporting 2006 nonconfidential data lists five US producers of NP with an aggregate production volume ranging from 100 to 500 million pounds. The chemical industry reported that US demand for nonylphenol was 235 million pounds in 1999.[11]

HEALTH AND ECOLOGICAL CONCERNS

Alkylphenols, including NPE and NP have been detected in the natural environment, including ambient air, sewage treatment plant effluent, sediment, soil and surface waters, in wildlife, household dust and human tissues. Nonylphenol and nonylphenol ethoxylates are toxic to aquatic organisms, and the breakdown products of nonylphenol ethoxylates (NP and shorter-chained ethoxylates) are more toxic and more persistent than their parent chemicals.

NP has been shown to have estrogenic effects in a number of aquatic organisms,[12, 13] and in human breast tumor cells and rats.[14] The isomer 4-*n*-nonylphenol has demonstrated endocrine disrupting effects in four key cell mechanisms in vitro.[15]

REGULATORY AND VOLUNTARY INTIATIVES TO REDUCE USE OF AND EXPOSURE TO NONYLPHENOL AND NONYLPHENOL ETHOXYLATES

US EPA

As part of an effort to enhance the agency's chemical management plans under the Toxic Substances Control Act (TSCA) the US Environmental Protection Agency is currently developing an Action Plan on NP and NPE.

European Union

The European Union prohibits the sale or use of nonylphenol and nonylphenol ethoxylates in concentrations greater than 0.1% by weight for the following uses:

- industrial and institutional cleaning (except controlled closed dry cleaning systems where the washing liquid is recycled or incinerated and cleaning systems with special treatment where the washing liquid is recycled or incinerate*);*
- domestic cleaning;
- textiles and leather processing (except processing with no release into waste water and systems with special treatment where the process water is pretreated to remove the organic fraction completely prior to biological waste water treatment);

- emulsifier in agricultural teat dips; metal working (except uses in controlled closed systems where the washing liquid is recycled or incinerated);
- manufacturing of pulp and paper; cosmetic products; other personal care products (except spermicides); and
- co-formulations in pesticides and biocides.[16]

Canada

In 2001, Canada added nonylphenol and its ethoxylates to the list of toxic substances under the Canadian Environmental Protection Act and in 2004 required implementation of pollution prevention plans for NP and NPE contained in products, including a 95% reduction in use of NP and NPE by the end of 2010.[17]

Voluntary

Numerous companies, including chemical manufacturers, product formulators, retailers and distributors and institutional users, have earned recognition through US EPA's Safer Detergent Stewardship Initiative (SDSI) by manufacturing or using only "safer" surfactants in their cleaning products. Under the SDSI program, NPE do not meet the definition of "safer surfactant."[18] In 2006, Wal-Mart announced efforts to encourage product suppliers to find alternatives to three "priority chemicals," including nonylphenol ethoxylates.[19]

ALTERNATIVES

An assessment of alternatives to NP and NPE conducted for Environment Canada found a number of available alternative surfactants currently in use and on the market. The report concluded that the most widely-used alternatives, alcohol ethoxylates (AE), are equivalent in performance to NPE, and in some cases outperform NPE in most sectors including cleaning products, and that AE have a better environmental profile than NPE in that:

- AE are readily and ultimately biodegradable, while NPE are ultimately but not readily biodegradable.
- The biodegradation intermediates of AE are less toxic than the parent surfactants while the biodegradation intermediates of NPE are more toxic than the parent surfactants.
- The predicted chronic no-effect value for AE is 110µg/L; for NP it is 1µg/L.

The report suggests that octylphenol ethoxylates (OPE) are not suitable alternatives to NPE because they exhibit similar toxicological profile and environmental fate characteristics as NPE and because octylphenol (the building block and degradation product of OPE) also shows evidence of estrogenic activity.[20]

PREREQUISITES FOR DESIGNATION OF NONYLPHENOL AND NONYLPHENOL ETHOXYLATES AS A PRIORITY CHEMICAL / FINDINGS OF FACT

CHEMICALS OF HIGH CONCERN LIST

The chemical class **nonylphenol, nonylphenol ethoxylates and related substances** appears on the Chemicals of High Concern list[21] published by the department because this chemical family has been designated as:

- persistent, bioaccumulative and toxic on the OSPAR (Oslo-Paris Convention for the Protection of the Marine Environment of the North-East Atlantic) list of Chemicals for Priority Action; and
- an endocrine disruptor on the OSPAR list of Chemicals for Priority Action.

Phenol, nonyl- (CAS RN 25154-52-3) appears on the Chemicals of High Concern list because it has been designated as a:

- a persistent, bioaccumulative toxin on the OSPAR list of Chemicals of Concern; and
- a category 1 endocrine disruptor, "evidence of endocrine disruption activity" in the European Commission Communication on a Community Strategy for Endocrine Disruptors; and

Phenol, nonyl-4, branched (CAS RN 84852-15-3) appears on the Chemicals of High Concern list because it has been designated as:

- persistent, bioaccumulative and toxic on the OSPAR list of Chemicals of Concern.

Nonylphenolethoxylate (CAS RN 9016-45-9) appears on the Chemicals of High Concern list because it has been designated as:

- persistent, bioaccumulative and toxic on the OSPAR list of Chemicals of Concern.

CRITERIA FOR DESIGNTATION

Biomonitoring. The chemical has been found through biomonitoring to be present in human blood, including umbilical cord blood, breast milk, urine or other bodily tissues or fluids, specifically:

- NP has been detected in the serum of pregnant women in Canada,22 in the urine of adults in the US,23 in the breast milk of women in Italy,24 and in the adipose tissue of women in Spain.25

Home Environment. The chemical has been found through sampling and analysis to be present in household dust, indoor air, drinking water or elsewhere in the home environment, specifically:

- Researchers sampling indoor air and dust for endocrine disrupting compounds found alkylphenols and ethoxylates among the most abundant compounds detected, with

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4-nonylphenol (a metabolite) detected in 100% of indoor air samples at high concentrations (90th percentile) relative to other compounds in the study.[26]

Ecological Sampling. The chemical has been found through monitoring to be present in fish, wildlife or the natural environment, specifically:

- NPE and their degradation products have been detected in wastewater, ambient air, surface water and sediments.[27] In a study of organic wastewater contaminants in US streams, 4-nonylphenol was one of the most frequently-detected compounds.[28]
- Researchers sampled a variety of species of fish collected from two major regions in Michigan and found detectable concentrations of NP in 41% of samples across all sites and species with a range of 3.3 to 29.1 ng of NP/g.[29]

Consumer Products. The chemical is present in a consumer product used or present in the home, specifically:

- Household detergents, cleaners and degreasers; personal care products and cosmetics; home maintenance products.[30, 31]

HPV. The chemical has been identified as a High Production Volume chemical by the federal Environmental Protection Agency.

- HPV chemicals are classified as those chemicals produced or imported in the United States in quantities of 1 million pounds or more per year. The US Environmental Protection Agency non-confidential IUR Production Volume Information database for 2006 shows production (manufacture and importation) of nonylphenol (CAS RN 84852-15-3) in the 100-500 million pound range and nonylphenol ethoxylates in the 10-50 million pound range (CAS RN 9016-45-9) and the 1-10 million pound range (CAS RN 127087-87-0).[32]

PURPOSE OF DESIGNATION

REQUEST FOR INFORMATION

The department is designating the chemical class nonylphenol and nonylphenol ethoxylates a priority chemical for the purpose of requesting information related to the extent to which nonylphenol and nonylphenol ethoxylates are used in, and the likelihood that children will be exposed to, the chemical as a result of its presence in, the following consumer products:

- Household and commercial cleaning products,
- Cosmetics and personal care products, and
- Home maintenance products sold, marketed to, or intended for use by consumers.

BASIS FOR DEPARTMENT ACTION

DEFINITION OF CHILDREN'S PRODUCTS

The products listed in the department's request for information in the proposed rule meet the definition of "children's products" under 38 MRSA §1691(7) because household and commercial cleaning products, home maintenance product and cosmetics and personal care products are products that when used in a home or commercial setting frequented by children (e.g., a school or daycare center), they "will likely result in a child's or fetus's being exposed" to NP and NPE.

NEED FOR INFORMATION REGARDING NP AND NPE USE IN CHILDREN'S PRODUCTS

Information available to the department indicates that NP and NPE are used in consumer products intended for household use that will likely result in children being exposed to the chemical class, however, there is some indication that these uses have decreased (household cleaning products) or may have been eliminated (personal care products). The department is requesting information to assess how widely this chemical class is used in consumer products sold in Maine.

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REFERENCES

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June 29, 2010

Commissioner David Littell
Maine Department of Environmental Protection
17 State House Station
Augusta, ME 04333

Dear Commissioner Littell:

38 MRSA §1694 requires that the designation of a "priority chemical" under Maine's Toxic Chemicals in Children's Products law be made in concurrence with the Department of Health and Human Services, Maine Center for Disease Control and Prevention (ME-CDC). By this letter and accompanying document, ME-CDC is informing the Department of Environmental Protection (ME-DEP) of its concurrence with its proposed designation of Nonylphenol and Nonylphenol Ethoxylates as priority chemicals.

Under 38 MRSA §1694, the ME-DEP may designate a chemical as a priority chemical if the Commissioner finds any of the following:

A. The chemical has been found through biomonitoring to be present in human blood, including umbilical cord blood, breast milk, urine or other bodily tissues or fluids;
B. The chemical has been found through sampling and analysis to be present in household dust, indoor air, drinking water or elsewhere in the home environment;
C. The chemical has been found through monitoring to be present in fish, wildlife or the natural environment;
D. The chemical is present in a consumer product used or present in the home;
E. The chemical has been identified as a high production volume chemical by the federal Environmental Protection Agency; or
F. The sale or use of the chemical or a product containing the chemical has been banned in another state within the United States.

ME-CDC's toxicologist, Dr. Deborah Rice, has reviewed ME-DEP's basis statement for designating Nonylphenol and Nonylphenol Ethoxylates as priority chemicals as well as a review of relevant scientific literature, and prepared the attached document providing our Agency's justification for concurrence based on evidence that these chemicals meet the criteria A – D above.

Sincerely,

Dora Anne Mills

Dora Anne Mills, M.D., M.P.H.
State Health Officer and Director,
Maine Center for Disease Control and Prevention

cc: Andrew E. Smith, SM, ScD, State Toxicologist, ME-CDC

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Rationale for Concurrence by Maine Center for Disease Control and Prevention on the Designation of Nonylphenol and Nonylphenol Ethoxylates as a Priority Chemical

Prepared by Deborah Rice, PhD, Toxicologist

Maine Center for Disease Control and Prevention

June 29, 2010

Background

Under 38 MRSA §1694, the Commissioner of the Maine Department of Environmental Protection (ME-DEP) may designate a *chemical of high concern* as a *priority chemical* if the Commissioner finds any of the following:

A. The chemical has been found through biomonitoring to be present in human blood, including umbilical cord blood, breast milk, urine or other bodily tissues or fluids;

B. The chemical has been found through sampling and analysis to be present in household dust, indoor air, drinking water or elsewhere in the home environment;

C. The chemical has been found through monitoring to be present in fish, wildlife or the natural environment;

D. The chemical is present in a consumer product used or present in the home;

E. The chemical has been identified as a high production volume chemical by the federal Environmental Protection Agency; or

F. The sale or use of the chemical or a product containing the chemical has been banned in another state within the United States.

Once a chemical is listed as a priority chemical, the ME-DEP may require disclosure of information about the presence of the chemical in children's products (§1695) and prohibit sales of children's products including this chemical (§1696).

38 MRSA §1694 requires that the designation of a chemical as a *priority* chemical be made in concurrence with the Department of Health and Human Services, Maine Center for Disease Control and Prevention (ME-CDC).

The ME-DEP has proposed to list the chemicals *nonylphenol and nonylphenol ethoxylates* as a priority chemical. The Agency has requested that ME-CDC review the Department's draft *Basis Statement for Chapter 883 Designation of Nonylphenol and Nonylphenol Ethoxylates as a*

Priority Chemical and Safer Chemical Program Support Document for the Designation as a Priority Chemical of Nonylphenol and Nonylphenol Ethoxylates. [1]

ME-CDC concurs that it is appropriate to designate nonylphenol (NP) and nonylphenol ethoxylates (NPE) as a priority chemical under 38 MRSA §1694. In reaching its decision, ME-CDC performed its own review of the scientific literature relevant to findings under 38 MRSA §1694 (A), (B), (C), and (D), which are content areas within the expertise of the ME-CDC. ME-CDC also reviewed the evidence that NP, a degradation product of NPE, is an endocrine disruptor and a reproductive and developmental toxicant, which are criteria for designating a *chemical of high concern.* Since chemicals may be classified as of *high concern* for reasons other than human health hazard (i.e., persistent and bioaccumulative), ME-CDC viewed it appropriate to briefly review the toxicity data as well.

Overview of the chemical class nonylphenol and nonylphenol ethoxylates

NP are widely used for the synthesis of NPE, nonionic surfactants with a worldwide annual production in the hundreds of thousands of tons. NP are also used in the manufacture of plastics such as polystyrene and polyvinyl chloride, as inert ingredients in pesticides, and may be present in rubber and resins. The major source of NP in the environment is the microbial degradation of NPE, and NP have been detected in river water, sewage sludge, and drinking water (Ye *et al.*, 2007).

NP are a class of chemicals having a phenol ring attached to nine carbon atoms. The chain may be attached to the ring in one of three positions: ortho (*o* or 2); meta (*m* or 3); or para (*p* or 4). The alkyl chain can be a linear (*n*-) chain, or a complex branched chain. The commercial product is a mix of isomers, predominantly branched alkyl chain isomers of 4-NP, 4-tert-NP (Ye *et al.*, 2007). As many as 100 isomers have been reported in various environmental media (Thiele *et al.*, 2004; Eganhouse *et al.*, 2009; Ieda *et al.*, 2005; Ruβ *et al.*, 2005).

The primary concern for these compounds is due to their ability to bind to the estrogen receptor and thereby mimic the effects of estrogen. In an *in vitro* assay for estrogenic activity in fish, both NP and NPE were active (Jobling and Sumpter, 1993). Of the isomers tested, the *para* (4)-substituted isomers were active, whereas the *ortho* (2) and *meta* (3) isomers were not. There is also evidence that various 4-NP branched-chain isomers have differential estrogenic activity (Saito *et al.*, 2007). Biodegradation of NPE results in shortening of the ethyxylate chain into more toxic ethoxylates and NP, although NPE is generally considered to be less toxic than NP (Bakke *et al.*, 2003).

Most research studies, described below, do not specify which form of NP is being studied. It is presumed that most used the mixed isomer commercial product; although a small number of studies used the linear *(n-)* form.

[1] Draft Basis Statement for Chapter 883 Designation of Nonylphenol and Nonylphenol Ethoxylates as a Priority Chemical and Safer Chemicals Program Support Document for the Designation as a Priority Chemical of Nonylphenol and Nonylphenol Ethoxylates. Maine Department of Environmental Protection, Bureau of Remediation and Waste Management, 21 April, 2010.

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Evidence that nonylphenol may be classified as an endocrine disruptor and a developmental and reproductive toxicant

NP acts as an estrogenic chemical, binding to the estrogen receptor and producing estrogenic effects in *in vitro* systems in a number of mammalian and non-mammalian species and tissues (Soto *et al.*, 1991, 1995; Shelby *et al.*, 1996; Laws *et al.*, 2000; Kwack *et al.*, 2002; Blair *et al.*, 2000; Danzo, 1997; Bonefeld-Jorgensen *et al.*, 2007; Vivacqua *et al.*, 2003). The NPE degradation product 4-nonylphenoldiethoxylate also has estrogenic properties in standard *in vitro* systems (White *et al.*, 1994). NP also exhibits estrogenic effects on standard estrogenic assays in the whole animal, including effects on uterine weight, time to puberty, and cancer tissue (Laws *et al.*, 2000; Odum *et al.*, 1999; Kwack *et al.*, 2002; Watanabe *et al.*, 2004; Kim *et al.*, 2002).

Gestational exposure to NP produced effects on mammary gland development and changes in hormone receptor densities (Moon *et al.*, 2007). Female rats exposed to NP in the early postnatal period showed altered estrus cycles and abnormal reproductive function (Nagao *et al.*, 2000). Exposure to NP in pregnant rats produced changes in estrogen-specific mRNA and protein levels in dams and fetuses, and decreased estrogen receptor density in the fetus (Hong *et al.*, 2004). In a study in human first-trimester placental tissue, exposure of chorionic villous to very low levels of NP produced estrogen-mimicking effects, including trophoblast differentiation and cell apoptosis (programmed cell death) (Bechi *et al.*, 2006). NP was more active and for a longer period than estrogen itself. A follow-up study (Bechi *et al.*, 2010) found that NP interfered with secretion of specific cytokines, chemicals that play a critical role in pregnancy, particularly during development of the placenta and implantation of the conceptus. These results raise concern about the effects of exposure to NP on the maintenance of pregnancy.

NP affect reproductive function in males as well, affecting sperm production (Adeoya-Osiguwa *et al.*, 2003), testicular growth (Jobling *et al.*, 1996), epididymus weight and reproductive hormone levels (Han *et al.*, 2004; Wu *et al.*, 2010; Gong and Han, 2006) in adult animals. Epididymal weight was decreased in offspring of rats exposed to NP during gestation (Hossaini *et al.*, 2001), and rats exposed during the early postnatal period exhibited changes in gonadal structure (Nagao *et al.*, 2000). NP increased apoptosis in Sertoli cells, in conjunction with morphological changes and decreased cell viability (Gong *et al.*, 2009; Wang *et al.*, 2003). Exploration of the mechanisms of apoptosis by NP identified several possible pathways (Wu *et al.*, 2009; Gong *et al.*, 2009).

NP affects organ systems in addition to the reproductive system, including as a result of developmental exposure. NP has a direct effect on the immune system (lymphocytic proliferation) by mechanisms independent of the estrogen or progesterone receptors (Iwata *et al.*, 2004; Mao *et al.*, 2008). *In utero* and postnatal exposure to NP also produced immune effects (changes in splenic natural killer cells and splenocyte subpopulations), with no effects observed in the dams (Karrow *et al.*, 2004). NP also produced apoptosis in thymocytes by specific mechanisms (Yao *et al.*, 2006), providing further evidence for disruption of the immune system by NP.

Researchers have also explored the effects of NP on the developing nervous system. NP induces death of murine (rat or mouse) (Kudo *et* al., 2004; Mao *et al.*, 2008) and human (Kim *et* al.,

2006) stem cells via a specific apopototic mechanism, suggesting that NP may affect neurogenesis in the central nervous system. There is also evidence that developmental exposure to NP affects thyroid function. *In utero* exposure resulted in changes in circulating levels of thyroid hormone (T_3) and/or thyroid stimulating hormone (TSH) in both sexes, in addition to changes in levels of certain reproductive hormones (Nagao *et al.*, 2001). NP has also been demonstrated to affect enzymes (aromatase) and receptors (aryl hydrocarbon and pregnane X receptor) involved in the synthesis and regulation of a number of other hormones in addition to reproductive hormones (Masuyama *et al.*, 2000; Bonefeld-Jørgensen *et al.*, 2007).

Evidence that nonylphenol is present in human tissue (38 MRSA §1694-A)

A recent review identified 20 studies in which NP was measured in human tissue (Lopez-Espinosa *et al.*, 2009). NP was detected in 18 of the studies, including in breast milk and cord blood, and blood, urine, and adipose tissue of adults. Only one study was performed in occupationally-exposed individuals, with the other studies representing environmental exposure. NP was generally detected in 50-100% of samples. A study in the United States measured 4-*n*-nonylphenol, the linear chain NP isomer, in 394 urine samples of 394 individuals >= 6 years of age from NHANES III (Calafat *et al.*, 2005). NP was detected in 51% of samples. The authors state that the isomer they measured represents a small percentage of total NP in the commercial mixture; so the total NP present may have been underestimated. Studies in Japan and Italy found NP in 100% of breast milk samples, and four studies found NP present in 26-86% of cord blood samples. A study in Taiwan compared levels of NP in maternal and umbilical cord blood in maternal-fetal pairs; levels in the mothers' blood generally exceeded those in the infant (Chen *et al.*, 2008).

Evidence for exposure to nonylphenol and nonylphenol ethoxylates by infants and children (38 MRSA §1694-B, C, and D)

NP and NP compounds have been found to be present in human food, including fresh fruit and vegetables (Yang and Ding, 2005), corn cereals (Carabias-Martinez *et al.*, 2006), eggs and milk (Shao *et al.*, 2007), and baby food purees of fruit and meat (Li *et al.*, 2008). A study in Germany identified 4-NP in a variety of foods, including fish, milk, cheese, eggs, pasta, and fruits and vegetables (Guenther *et al.*, 2002). Levels did not apparently correlate with the fat content of the product. The pattern of 4-NP in the various foods was similar to that of the commercial mixture. The authors suggest that there are multiple sources of NPs in food, including use of NPs as pesticides and surfactants, and in packaging material. NP and NPE are found in fish (Tsuda *et al.*, 2000), including those in U.S. waters (Keith *et al.*, 2001; Kannan *et al.*, 2003). An Italian study reported that levels of NP in breast milk correlated with fish intake in the mothers (Ademollo *et al.*, 2008).

NP and NPE have been detected in indoor air and house dust in a majority of homes tested in the U.S (Rudel *et al.*, 2001, 2003). NP have been found in food packaging, including polystyrene, polyolifins, and polyesters, cellulose and cellulose esters, rubbers, and coated paper (Fernandes *et al.*, 2008) and rubber products (Ozaki and Baba, 2003). A review by Muncke (2009) reported NP in a variety of foods from a number of container types, presumably at least in part as a result of oxidation of the antioxidant additive trisnonylphenol phosphate.

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